36

21 C.F.R. § 202.1

Effective: [See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter C. Drugs: General
Part 202. Prescription Drug Advertising (Refs & Annos)

§ 202.1 Prescription-drug advertisements.

(a)(1) The ingredient information required by section 502(n) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names.

(2) The order of listing of ingredients in the advertisement shall be the same as the order of listing of ingredients on the label of the product, and the information presented in the advertisement concerning the quantity of each such ingredient shall be the same as the corresponding information on the label of the product.

(3) The advertisement shall not employ a fanciful proprietary name for the drug or any ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition, when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The advertisement shall not feature inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) The advertisement shall not designate a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(b)(1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured in the advertisement for the drug; but, except as provided below in this subparagraph, the established name need not be used with the proprietary name or designation in the running text of the advertisement. On any page of an advertisement in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text in association with such proprietary name or designation and in the same type size used in the running text: *Provided, however*, That if the proprietary name or designation is used in the running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such running text. If any advertisement includes a column with running text containing detailed information as to composition, prescribing, side effects, or contraindications and the proprietary name or designation is used in such column but is not featured above or below the column, the established name shall be used at least once in such column of running text in association with such proprietary name or designation and in the same type size used in such column of running text: *Provided, however*, That if the proprietary name or designation is used in such column of running text in larger size type, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or

designation in such column of running text. Where the established name is required to accompany or to be used in association with the proprietary name or designation, the established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of" preceding the established name, by brackets surrounding the established name, or by other suitable means.

(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

(c) In the case of a prescription drug containing two or more active ingredients, if the advertisement bears a proprietary name or designation for such mixture and there is no established name corresponding to such proprietary name or designation, the quantitative ingredient information required in the advertisement by section 502(n) of the act shall be placed in direct conjunction with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name.

(d)(1) If the advertisement employs one proprietary name or designation to refer to a combination of active ingredients present in more than one preparation (the individual preparations differing from each other as to quantities of active ingredients and/or the form of the finished preparation) and there is no established name corresponding to such proprietary name or designation, a listing showing the established names of the active ingredients shall be placed in direct conjunction with the most prominent display of such proprietary name or designation. The prominence of this listing of active ingredients shall bear a reasonable relationship to the prominence of the proprietary name and the relationship between such proprietary name or designation, and the listing of active ingredients shall be made clear by use of such phrase as "brand of", preceding the listing of active ingredients.

(2) The advertisement shall prominently display the name of at least one specific dosage form and shall have the quantitative ingredient information required by section 502(n) of the act in direct conjunction with such display. If other dosage forms are listed in the advertisement, the quantitative ingredient information for such dosage forms shall appear in direct conjunction and in equal prominence with the most prominent listing of the names of such dosage forms.

(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) When required. All advertisements for any prescription drug ("prescription drug" as used in this section means drugs defined in section 503(b)(1) of the act and § 201.105, applicable to drugs for use by man and veterinary drugs, respectively), except advertisements described in paragraph (e)(2) of this section, shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section "side effects, contraindications" include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.) and effectiveness. Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to side effects and contraindications.

(2) Exempt advertisements. The following

advertisements are exempt from the requirements of paragraph (e)(1) of this section under the conditions specified:

(i) Reminder advertisements. Reminder advertisements are those which call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product. These reminder advertisements shall contain only the proprietary name of the drug product, if any; the established name of the drug product, if any; the established name of each active ingredient in the drug product; and, optionally, information relating to quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug product. If the Commissioner finds that there is evidence of significant incidence of fatalities or serious injury associated with the use of a particular prescription drug, he may withdraw this exemption by so notifying the manufacturer, packer, or distributor of the drug by letter. Reminder advertisements, other than those solely intended to convey price information including, but not limited to, those subject to the requirements of § 200.200 of this chapter, are not permitted for a prescription drug product whose labeling contains a boxed warning relating to a serious hazard associated with the use of the drug product. Reminder advertisements which are intended to provide consumers with information concerning the price charged for a prescription for a drug product are exempt from the requirements of this section if they meet all of the conditions contained in § 200.200 of this chapter. Reminder advertisements, other than those subject to the requirements of § 200.200 of this chapter, are not permitted for a drug for which an announcement has been published pursuant to a review on the labeling claims for the drug by the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group, and for which no claim has been evaluated as higher than "possibly effective." If the Commissioner finds the circumstances are such that a reminder advertisement may be misleading to prescribers of drugs subject to NAS/NRC evaluation, such advertisements will not be allowed and the manufacturer, packer, or distributor will be notified either in the publication of the conclusions on the effectiveness of the drug or by letter.

(ii) Advertisements of bulk-sale drugs. Advertisements of bulk-sale drugs that promote sale of the drug in bulk packages in accordance with the practice of the trade solely to be processed, manufactured, labeled, or repackaged in substantial quantities and that contain no claims for the therapeutic safety or effectiveness of the drug.

(iii) Advertisements of prescription-compounding drugs. Advertisements of prescription-compounding drugs that promote sale of a drug for use as a prescription chemical or other compound for use by registered pharmacists in compounding prescriptions if the drug otherwise complies with the conditions for the labeling exemption contained in § 201.120 and the advertisement contains no claims for the therapeutic safety or effectiveness of the drug.

(3) Scope of information to be included; applicability to the entire advertisement.

(i) The requirement of a true statement of information relating to side effects, contraindications, and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement of a brief statement containing true information relating to side effects, contraindications, and effectiveness of the drug. If any part or theme of the advertisement would make the advertisement false or misleading by reason of the omission of appropriate qualification or pertinent information, that part or theme shall include the appropriate qualification or pertinent information, which may be concise if it is supplemented by a prominent reference on each page to the presence and location elsewhere in the advertisement of a more

complete discussion of such qualification or information.

(ii) The information relating to effectiveness is not required to include information relating to all purposes for which the drug is intended but may optionally be limited to a true statement of the effectiveness of the drug for the selected purpose(s) for which the drug is recommended or suggested in the advertisement. The information relating to effectiveness shall include specific indications for use of the drug for purposes claimed in the advertisement; for example, when an advertisement contains a broad claim that a drug is an antibacterial agent, the advertisement shall name a type or types of infections and microorganisms for which the drug is effective clinically as specifically as required, approved, or permitted in the drug package labeling.

(iii) The information relating to side effects and contraindications shall disclose each specific side effect and contraindication (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.; see paragraph (e)(1) of this section) contained in required, approved, or permitted labeling for the advertised drug dosage form(s): *Provided, however*,

(a) The side effects and contraindications disclosed may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement to the extent that such limited disclosure has previously been approved or permitted in drug labeling conforming to the provisions of §§ 201.100 or 201.105; and

(b) The use of a single term for a group of side effects and contraindications (for example, "blood dyscrasias" for disclosure of "leukopenia," "agranulocytosis," and "neutropenia") is permitted only to the extent that the use of such a single term in place of disclosure of each specific side effect and contraindication has been previously approved or permitted in drug labeling conforming to the provisions of §§ 201.100 or 201.105.

(4) Substance of information to be included in brief summary.

(i)(a) An advertisement for a prescription drug covered by a new-drug application approved pursuant to section 505 of the act after October 10, 1962 or section 512 of the act after August 1, 1969, or any approved supplement thereto, shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement. The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

(b) If a prescription drug was covered by a new-drug application or a supplement thereto that became effective prior to October 10, 1962, an advertisement may recommend or suggest:

(1) Uses contained in the labeling accepted in such new-drug application and any effective, approved, or permitted supplement thereto.

(2) Additional uses contained in labeling in commercial use on October 9, 1962, to the extent that such uses did not cause the drug to be an unapproved "new drug" as "new drug" was defined in section 201(p) of the act as then in force, and to the extent that such uses would be permitted were the drug subject to paragraph (e)(4)(iii) of this section.

(3) Additional uses contained in labeling in current commercial use to the extent that such uses do not cause the drug to be an unapproved "new drug" as defined in section 201(p) of

the act as amended or a "new animal drug" as defined in section 201(v) of the act as amended.

The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

(ii) In the case of an advertisement for a prescription drug other than a drug the labeling of which causes it to be an unapproved "new drug" and other than drugs covered by paragraph (e)(4)(i) of this section, an advertisement may recommend and suggest the drug only for those uses contained in the labeling thereof:

(a) For which the drug is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of such drugs; or

(b) For which there exists substantial evidence of safety and effectiveness, consisting of adequate and well-controlled investigations, including clinical investigations (as used in this section "clinical investigations," "clinical experience," and "clinical significance" mean in the case of drugs intended for administration to man, investigations, experience, or significance in humans, and in the case of drugs intended for administration to other animals, investigations, experience, or significance in the specie or species for which the drug is advertised), by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses; or

(c) For which there exists substantial clinical experience (as used in this section this means substantial clinical experience adequately documented in medical literature or by other data (to be supplied to the Food and Drug Administration, if requested)), on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses; or

(d) For which safety is supported under any of the preceding clauses in paragraphs (e)(4)(iii)(a), (b), and (c) of this section and effectiveness is supported under any other of such clauses.

The advertisement shall present information relating to each specific side effect and contraindication that is required, approved, or permitted in the package labeling by §§ 201.100 or 201.105 of this chapter of the drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section.

(5) "True statement" of information. An advertisement does not satisfy the requirement that it present a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if:

(i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or

(ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by section 502(n) of the act and this information is not fairly balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug; *Provided, however*, That no advertisement shall be considered to be in violation of this section if the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety.

(iii) It fails to reveal facts material in the light of its representations or material with respect to

consequences that may result from the use of the drug as recommended or suggested in the advertisement.

(6) Advertisements that are false, lacking in fair balance, or otherwise misleading. An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it:

(i) Contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in this section patients means humans and in the case of veterinary drugs, other animals), safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraphs (e)(4)(ii)(b) and (c) of this section) whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

(ii) Contains a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience.

(iii) Contains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information, or contains literature references or quotations that are significantly more favorable to the drug than has been demonstrated by substantial evidence or substantial clinical experience.

(iv) Contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.

(v) Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

(vi) Contains references to literature or studies that misrepresent the effectiveness of a drug by failure to disclose that claimed results may be due to concomitant therapy, or by failure to disclose the credible information available concerning the extent to which claimed results may be due to placebo effect (information concerning placebo effect is not required unless the advertisement promotes the drug for use by man).

(vii) Contains favorable data or conclusions from nonclinical studies of a drug, such as in laboratory animals or in vitro, in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

(viii) Uses a statement by a recognized authority that is apparently favorable about a drug but fails to refer to concurrent or more recent unfavorable data or statements from the same authority on the same subject or subjects.

(ix) Uses a quote or paraphrase out of context to convey a false or misleading idea.

(x) Uses literature, quotations, or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim.

(xi) Uses literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling.

(xii) Offers a combination of drugs for the treatment of patients suffering from a condition amenable to treatment by any of the

components rather than limiting the indications for use to patients for whom concomitant therapy as provided by the fixed combination drug is indicated, unless such condition is included in the uses permitted under paragraph (e)(4) of this section.

(xiii) Uses a study on normal individuals without disclosing that the subjects were normal, unless the drug is intended for use on normal individuals.

(xiv) Uses "statistics" on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that suggests either that such "statistics" are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

(xv) Uses erroneously a statistical finding of "no significant difference" to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference.

(xvi) Uses statements or representations that a drug differs from or does not contain a named drug or category of drugs, or that it has a greater potency per unit of weight, in a way that suggests falsely or misleadingly or without substantial evidence or substantial clinical experience that the advertised drug is safer or more effective than such other drug or drugs.

(xvii) Uses data favorable to a drug derived from patients treated with dosages different from those recommended in approved or permitted labeling if the drug advertised is subject to section 505 of the act, or, in the case of other drugs, if the dosages employed were different from those recommended in the labeling and generally recognized as safe and effective. This provision is not intended to prevent citation of reports of studies that include some patients treated with dosages different from those authorized, if the results in such patients are not used.

(xviii) Uses headline, subheadline, or pictorial or other graphic matter in a way that is misleading.

(xix) Represents or suggests that drug dosages properly recommended for use in the treatment of certain classes of patients or disease conditions are safe and effective for the treatment of other classes of patients or disease conditions when such is not the case.

(xx) Presents required information relating to side effects or contraindications by means of a general term for a group in place of disclosing each specific side effect and contraindication (for example employs the term blood dyscrasias instead of "leukopenia," "agranulocytosis," "neutropenia," etc.) unless the use of such general term conforms to the provisions of paragraph (e)(3)(iii) of this section.

Provided, however, That any provision of this paragraph shall be waived with respect to a specified advertisement as set forth in a written communication from the Food and Drug Administration on a petition for such a waiver from a person who would be adversely affected by the enforcement of such provision on the basis of a showing that the advertisement is not false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act. A petition for such a waiver shall set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of this paragraph from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act.

(7) Advertisements that may be false, lacking in fair balance, or otherwise misleading. An advertisement may be false, lacking in fair balance, or otherwise misleading or otherwise violative of section 502(n) of the act if it:

(i) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions.

(ii) Uses the concept of "statistical

significance" to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results.

(iii) Uses statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

(iv) Uses tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied; for example, by failing to label abscissa and ordinate so that the graph creates a misleading impression.

(v) Uses reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles of statistical theory, methodology, applied practice, and inference, or that are derived from clinical studies the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretations, or evaluations.

(vi) Contains claims concerning the mechanism or site of drug action that are not generally regarded as established by scientific evidence by experts qualified by scientific training and experience without disclosing that the claims are not established and the limitations of the supporting evidence.

(vii) Fails to provide sufficient emphasis for the information relating to side effects and contraindications, when such information is contained in a distinct part of an advertisement, because of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.

(viii) Fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(ix) Fails to provide adequate emphasis (for example, by the use of color scheme, borders, headlines, or copy that extends across the gutter) for the fact that two facing pages are part of the same advertisement when one page contains information relating to side effects and contraindications.

(x) In an advertisement promoting use of the drug in a selected class of patients (for example, geriatric patients or depressed patients), fails to present with adequate emphasis the significant side effects and contraindications or the significant dosage considerations, when dosage recommendations are included in an advertisement, especially applicable to that selected class of patients.

(xi) Fails to present on a page facing another page (or on another full page) of an advertisement on more than one page, information relating to side effects and contraindications when such information is in a distinct part of the advertisement.

(xii) Fails to include on each page or spread of an advertisement the information relating to side effects and contraindications or a prominent reference to its presence and location when it is presented as a distinct part of an advertisement.

(xiii) Contains information from published or unpublished reports or opinions falsely or misleadingly represented or suggested to be authentic or authoritative.

(f) to (i) [Reserved]

(j)(1) No advertisement concerning a particular prescription drug may be disseminated without prior approval by the Food and Drug Administration if:

(i) The sponsor or the Food and Drug Administration has received information that has not been widely publicized in medical

literature that the use of the drug may cause fatalities or serious damage;

(ii) The Commissioner (or in his absence the officer acting as Commissioner), after evaluating the reliability of such information, has notified the sponsor that the information must be a part of the advertisements for the drug; and

(iii) The sponsor has failed within a reasonable time as specified in such notification to present to the Food and Drug Administration a program, adequate in light of the nature of the information, for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements.

If the Commissioner finds that the program presented is not being followed, he will notify the sponsor that prior approval of all advertisements for the particular drug will be required. Nothing in this paragraph is to be construed as limiting the Commissioner's or the Secretary's rights, as authorized by law, to issue publicity, to suspend any new-drug application, to decertify any antibiotic, or to recommend any regulatory action.

(2) Within a reasonable time after information concerning the possibility that a drug may cause fatalities or serious damage has been widely publicized in medical literature, the Food and Drug Administration shall notify the sponsor of the drug by mail that prior approval of advertisements for the drug is no longer necessary.

(3) Dissemination of an advertisement not in compliance with this paragraph shall be deemed to be an act that causes the drug to be misbranded under section 502(n) of the act.

(4) Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment. If the advertiser is notified that the submitted advertisement is not in violation and, at some subsequent time, the Food and Drug Administration changes its opinion, the advertiser will be so notified and will be given a reasonable time for correction before any regulatory action is taken under this section. Notification to the advertiser that a proposed advertisement is or is not considered to be in violation shall be in written form.

(5) The sponsor shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter with respect to any determination that prior approval is required for advertisements concerning a particular prescription drug, or that a particular advertisement is not approvable.

(k) An advertisement issued or caused to be issued by the manufacturer, packer, or distributor of the drug promoted by the advertisement and which is not in compliance with section 502(n) of the act and the applicable regulations thereunder shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded under section 502(n) of the act.

(l)(1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor are hereby determined to be labeling as defined in section 201(m) of the act.

[40 FR 14016, March 27, 1975, as amended at 40

FR 58799, Dec. 18, 1975; 41 FR 48266, Nov. 2, 1976; 42 FR 15674, March 22, 1977; 54 FR 39635 , Sept. 27, 1989; 60 FR 38480, July 27, 1995; 64 FR 400, Jan. 5, 1999; 64 FR 26657, May 17, 1999]

Effective Date Note: At 44 FR 37467, June 26, 1979, § 202.1(e)(6)(ii) and (vii) were revised. At 44 FR 74817, Dec. 18, 1979, paragraphs (e)(6)(ii) and (vii) were stayed indefinitely. At 64 FR 500, Jan. 5, 1999, these paragraphs were amended. For the convenience of the user, paragraphs (e)(6)(ii) and (vii), published at 44 FR 37467, are set forth below:

(e) * * *

(6) * * *

(ii) Represents or suggests that a prescription drug is safer or more effective than another drug in some particular when the difference has not been demonstrated by substantial evidence. An advertisement for a prescription drug may not, either directly or by implication, e.g., by use of comparative test data or reference to published reports, represent that the drug is safer or more effective than another drug, nor may an advertisement contain a quantitative statement of safety or effectiveness (a) unless the representation has been approved as part of the labeling in a new drug application or biologic license, or (b) if the drug is not a new drug or biologic, unless the representation of safety or effectiveness is supported by substantial evidence derived from adequate and well-controlled studies as defined in § 314.111(a)(5)(ii) of this chapter, or unless the requirement for adequate and well-controlled studies is waived as provided in § 314.111(a)(5)(ii) of this chapter.

(vii) Suggests, on the basis of favorable data or conclusions from nonclinical studies of a prescription drug, such as studies in laboratory animals or in vitro, that the studies have clinical significance, if clinical significance has not been demonstrated. Data that demonstrate activity or effectiveness for a prescription drug in animal or in vitro tests and have not been shown by adequate and well-controlled clinical studies to pertain to clinical use may be used in advertising except that (a), in the case of anti-infective drugs, in vitro data may be included in the advertisement, if data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown" and (b), in the case of other drug classes, in vitro and animal data that have not been shown to pertain to clinical use by adequate and well-controlled clinical studies as defined in § 314.111(a)(5)(ii) of this chapter may not be used unless the requirement for adequate and well-controlled studies is waived as provided in § 314.111(a)(5)(ii) of this chapter.

SOURCE: 54 FR 39635, Sept. 27, 1989; 62 FR 51515, Oct. 1, 1997; 64 FR 400, Jan. 5, 1999, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 331, 352, 355, 360b , 371.

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Current through July 19, 2007; 72 FR 39581

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37

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(Cite as: 56 FR 60421)

If the comments persuade the agency that such a declaration on the product's principal display panel is necessary to not mislead consumers about the nature of a product, the agency will consider including a provision in the final rule requiring such a declaration.

f. Extended shelf life foods. Extended shelf life (ESL) is a term that describes a category of foods made possible by relatively recent developments in food processing and packaging technology. Generally, ESL describes a food that is unprocessed or minimally processed (in some cases, the product is cooked just as it would be by a consumer), and thus is not shelf stable, but that is packaged in such a manner so as to maintain its quality for an extended period of time when compared to traditional packaging methods. Such products are often refrigerated (many require refrigeration for safe distribution) and often rely on the use of "barrier" packaging and "modified or controlled atmospheres" in the package to retard aging of the food. For example, one such pasta product packaged in a barrier container with a modified atmosphere, reportedly has a refrigerated shelf life of 34 days (Ref. 52).

FDA notes that ESL do not meet the requirements of § 101.95(b) for the use of the term "freshly ." However, FDA recognizes that such products may be of a degree of quality similar to that of traditional prepared foods that could appropriately be labeled as "freshly ." FDA is requesting information on ESL foods that would enable it to determine whether any foods of this type merit use of the term "freshly ," and if so, what factors about such foods justify the use of the term in a nonmisleading manner. If the comments identify nonmisleading uses of the term "freshly " to describe ESL foods, the agency will consider explicitly limiting the proposed definition in § 101.95(b) to foods prepared and packaged by traditional means, and it will consider including provisions in the final rule permitting the use of the term "freshly " or other terms to describe foods prepared and packaged using ESL techniques.

B. Natural

The word "natural" is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome. In the past, FDA has not attempted to restrict use of the term "natural" except for added color, synthetic substances, and flavors under § 101.22. In its informal policy (Ref. 53), the agency has considered "natural" to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there. For example, the addition of beet juice to lemonade to make it pink would preclude the product being called "natural."

The meaning and use of the term "natural" on the label are of considerable interest to consumers and industry. Data suggest that uses of "natural" claims are confusing and misleading to consumers and frequently breach the public's legitimate expectations about their meaning. For example, two FTC reports (Refs. 54 and 55) cite numerous studies indicating a general lack of consumer

56 FR 60421-01, 1991 WL 250815 (F.R.)

(Cite as: 56 FR 60421)

understanding and scientific agreement about the meaning of the term.

The term "natural" is used, however, on a variety of products to mean a variety of things. Because of its widespread use, and the evidence that consumers regard many uses of this term as non-informative, the agency is considering establishing a definition for this term. FDA believes that if the term "natural" is adequately defined, the ambiguity surrounding use of the term that results in misleading claims could be abated.

In considering this issue, FDA has reviewed definitions of the term "natural" used by other government agencies, other countries, state governments, and industry. For example, USDA permits the use of the term "natural" on the labeling of meat and poultry products if: (1) They contain no artificial flavor or flavoring, coloring ingredient, chemical preservative, or any other artificial or synthetic ingredient, and (2) they and their ingredients are not more than "minimally processed." "Minimally processed" may include traditional processes such as smoking, roasting, freezing, drying, and fermenting. It may also include those processes that do not fundamentally alter the raw product and that only separate a whole, intact food into component parts such as grinding meat or pressing fruits to produce juices. Solvent extraction, acid hydrolysis, chemical bleaching, and other such relatively complex processes do not meet the criteria for minimal processing, and, thus, if they have occurred, the product would not be allowed by USDA to be labeled as "natural" (Ref. 56).

USDA's policy also provides that all labels of meat and poultry products bearing the term "natural" must be accompanied by a brief statement informing consumers that the product is natural because it contains no artificial ingredients and is only minimally processed. This statement may appear either directly beneath or beside all natural claims or may be placed elsewhere on the principal display panel provided an asterisk is used to tie the explanation to the claim. USDA has approved labels for "All Natural Wingettes" and "All Natural Chili."

Some of the definitions established by other government agencies, other countries, state governments, and industry are more restrictive than the USDA definition, while others are less so. There are numerous inconsistencies among the definitions as well as unanswered questions. Consequently, FDA has concluded that more consumer and industry input is needed before it can develop a definition for "natural." However, the agency notes that after considerable input from various groups, including scientists, consumers, industry, and regulatory professions, the ***60467** Federal Trade Commission (FTC) was unable to establish a definition for "natural." (See Refs. 54 and 55 and 48 FR 23270, May 24, 1983--Termination of rulemaking proceeding).

One possible meaning of the term "natural" as it applies to food is the absence of artificial or synthetic ingredients of any kind. This meaning, however, has been degraded by inappropriate use of the term in the marketplace. Should FDA establish a meaningful definition for "natural" so that this term has a common consumer understanding Because of the multiple and diverse meanings currently in

56 FR 60421-01, 1991 WL 250815 (F.R.)

(Cite as: 56 FR 60421)

use, establishing a definition for the term "natural" that will be readily accepted and understood will be difficult. The agency is seeking comments on whether it should define this term or should prohibit such claims entirely on the grounds that they are false or misleading.

In reaching a decision on any future FDA course of action, the agency seeks comments on how, or if, it should proceed in developing a definition for the term "natural." FDA is particularly interested in the views of consumers and industry on how "natural food" should be defined. Given past consumer confusion on what "natural" means, FDA seeks comments that provide examples of what a natural food is. In addition, FDA seeks comments on whether a food represented to be natural should be considered to be misbranded under section 403(a) of the act: (1) If it has undergone more than "minimal processing" (the agency also requests comments on what "minimal processing" means), or (2) if it contains any artificial or synthetic ingredients such as food and color additives.

How FDA proceeds will depend largely on response to the agency's concerns regarding a definition of the term "natural" and the identification of a suitable direction that the agency might explore in establishing a definition for such a term.

In addition to information on these broad uses of the term "natural," FDA is also seeking comment on how it distinguishes between artificial and natural flavors in § 101.22. The agency is concerned that its existing definition of "natural flavor" may not be consistent with the current interpretation of "natural" as implying minimal processing. For example, while removing the essential oil from a food is probably well understood to be minimal processing, and the oil is therefore a natural flavor of the food, it is less clear whether hydrolysis or enzymolysis of a food is minimal processing and therefore results in a natural flavor. The agency requests comments with substantiating information to provide a basis for a clearer, more appropriate distinction between natural and artificial flavors.

C. Organic

A review of the comments from consumers to the 1989 ANPRM on the use of the term "organic" demonstrated that consumer perceptions of the term encompass more than is generally intended by the term. Many of the comments suggested that they wanted either:

(1) Organic to mean "pesticide free" (organically grown) food;

(2) Label declaration of any pesticide, growth enhancer, fungicide, chemical, or radiation used; or

(3) At least label declaration of any potentially harmful pesticides and fertilizers used.

On November 28, 1990, Title XXI--Organic Certification, known as the "Organic

38

58 FR 2302-01

58 FR 2302-01, 1993 WL 1540 (F.R.)

(Cite as: 58 FR 2302)

for consumers to distinguish "fresh" product from "stale" product. One comment stressed that vacuum packaging is analogous to blast freezing in that both techniques allow foods to maintain their fresh state.

A small number of comments opposed permitting this use of the term "fresh." Another comment stated that the use of "fresh" in a guarantee statement (e.g., guaranteed fresh) should be restricted and should only be allowed if a food in question meets the definition for "fresh."

The agency has reviewed these comments and has concluded that the use of terms such as "freshness seal," "guaranteed fresh until," "and vacuum packed to preserve freshness," when they relate only to the function of the package and do not imply or suggest that the food itself is unprocessed, is outside the scope of this rulemaking. FDA acknowledges that these terms are used on numerous food products in the marketplace. To the extent that these terms might be used in any manner that is misleading, the agency will review specific situations on a case-by-case basis under the general misbranding provisions of section 403(a) of the act.

B. Natural

Although the use of the term "natural" on the food label is of considerable interest to consumers and industry, FDA's intent was not to establish a definition for "natural" in this rulemaking. However, the agency did note in the general principles proposal (56 FR 60421 at 60466) that, because of the widespread use of this term, and the evidence that consumers regard many uses of this term as noninformative, the agency would consider establishing a definition. Further, the agency stated that it believed that if the term "natural" is adequately defined, the ambiguity in the use of this term, which has resulted in misleading claims, could be abated. Therefore, the agency solicited comments on several issues that the agency must consider in deciding how to address the use of this term on foods, including: (1) Should the agency establish a definition for "natural" so that the term would have a common understanding among consumers, or should "natural" claims be prohibited altogether on the basis that they are false and misleading? (2) If a definition should be established, how should the agency define "natural?" (3) How should the agency proceed in developing a definition for "natural?" (4) Should a food that is represented as "natural" be considered to be misbranded if it has undergone more than minimal processing (and what constitutes minimal processing?), or if it contains any artificial or synthetic ingredients? In addition, FDA asked that identification of "natural" foods accompany the comments. FDA also solicited comments on how the agency distinguishes between artificial and natural flavors in § 101.22, and on how the agency should provide for a clearer, more appropriate distinction between natural and artificial flavors.

337. The comments provided a wide range of ideas for the agency to consider on the issue of developing a definition for "natural." Some comments stated that the term "natural" should be prohibited entirely on the basis that it generates confusion when used on the label or in the labeling of foods, and that the term is also false and misleading. Some comments stated that the agency should eliminate

58 FR 2302-01

58 FR 2302-01, 1993 WL 1540 (F.R.)

(Cite as: 58 FR 2302)

statements such as: "all natural," "100 percent natural," and made from "100 percent natural ingredients." Some comments suggested that the agency should not consider defining "natural" while it is implementing the mandatory requirements of the 1990 amendments.

Other comments suggested that the agency should address the use of the term "natural" in a separate rulemaking.

Some comments suggested that if FDA does establish a definition for the term "natural," it should encompass those foods that do not contain artificial or synthetic ingredients. A few comments stated that processing should not necessarily preclude a product from being deemed "natural." Other comments stated that the term "natural" and claims for natural ingredients should be permitted, provided that the manufacturer uses the term in a truthful, nonmisleading manner. Comments recommended that the use of natural color ingredients should not be precluded in foods that are represented as "natural." One comment suggested that manufacturers should be allowed to make claims for natural ingredients, regardless of any policy established for labeling finished foods as "natural." One comment stated that foods containing refined sugars should be allowed to be represented as "natural," whereas foods containing artificial sweeteners should not be represented as "natural."

None of the comments provided FDA with a specific direction to follow for developing a definition regarding the use of the term "natural." However, it was suggested that FDA should work with USDA to harmonize its definition for "natural."

A small percentage of comments addressed "minimal processing." Some of these comments proposed somewhat similar definitions under which "minimal processing" would refer to those processes that are familiar to consumers and that can be performed in the home (e.g., milling, grinding, baking). One comment suggested that "minimal processing" should include fermentation. Another comment implied that "minimal processing" should include traditional processes such as smoking, roasting, freeze drying, fermenting, and the separation of a product into component parts. The remaining comments defined "minimal processing" as those processes that do not fundamentally alter a raw food or any material derived from the raw food. Finally, some comments stated that FDA's current regulations for labeling natural flavors should not be changed.

After reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated. However, as the comments reflect, there are many facets of this issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term "natural." Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for "natural" at this time. The agency will maintain its current policy (as discussed in the general principles proposal (56 FR 60421 at 60466)) not to restrict the use of the term "natural" except for added color, synthetic substances, and flavors as provided in § 101.22.

58 FR 2302-01

58 FR 2302-01, 1993 WL 1540 (F.R.)

(Cite as: 58 FR 2302)

Additionally, the agency will maintain its policy (Ref. 32) regarding the use of "natural," as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlined in § 101.22.

**2408* C. Organic

In the general principles proposal (56 FR 60421 at 60467), FDA noted that responsibility for regulating use of the term "organic" was assigned by Congress to USDA in Title XXI--Organic Certification, also known as the "Organic Foods Production Act of 1990." The agency stated that it would defer issuing regulations governing the term "organic" until USDA had adopted appropriate regulations.

338. The majority of the comments addressing the use of "organic" as a food label term agreed with the agency's proposal to defer action until USDA has adopted appropriate regulations governing the term "organic." A small number of comments argued that defining the term "organic" was outside the scope of the 1990 amendments and, therefore, should not be part of this regulation.

However, other comments suggested that FDA should initiate rulemaking on the use of the term "organic" on food labels. Some of these comments suggested that the term "organic" should be applied to foods free of any artificial or synthetic ingredients, pesticides, growth enhancers, harmful fertilizers, or fungicides, and that it should not be applied to foods exposed to ionizing radiation. One comment stated that "organic" should not be allowed as a labeling term because there is no "scientifically acceptable" meaning for this term. Many of the consumer comments proposed that FDA adopt USDA's future definition for "organic" and consider adopting criteria established by the Organic Foods Production Act of 1990.

Most of the comments generally supported the agency's position as expressed in the proposal. Comments that opposed FDA's decision to defer rulemaking did not provide the agency with any justification why it should proceed with rulemaking before USDA has established regulations. Therefore, the agency continues to believe that it is best to defer rulemaking regarding the use of the term "organic" until USDA has adopted appropriate regulations. At that time, FDA will determine whether any regulations governing the term "organic" are necessary.

IX. Conclusions

After review and consideration of the comments received in response to the general principles and fat/cholesterol proposals, FDA concludes that it should amend parts 5 and 101 as set forth in those proposals and in the specific revisions to those proposed regulations discussed in this document. For the purposes of this final rule, certain changes, in addition to those discussed in this document, were made for editorial purposes, clarity, and consistency only. These changes do not amend any matter of substance.

39

sufficient information to make a product selection.

The agency agrees that the labeling schemes suggested by the comment would provide adequately descriptive labeling for some products and, as discussed in other comments, is requiring in the final regulation the declarations suggested. However, it does not agree that this scheme would ensure that all multiple-juice beverages would bear labels that are not misleading.

As discussed above, FDA finds that it is not necessary that all multiple-juice beverages identify each represented juice in the name of the product and declare the percentage of each represented juice. The agency has given examples of label statements that would not be misleading. However, FDA is not persuaded that the recommended schemes would ensure the labeling of multiple-juice beverages in which the named juice is not the predominant juice would provide enough information to describe the product for the consumer. FDA agrees with those comments that expressed concern that consumers are being misled into believing that named juices are present in greater amounts than is actually the case. The agency is aware of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount.

The agency notes that the regulation on the general principles for common and usual names provides in § 102.5(b) (21 CFR 102.5(b)) that when the proportion of a characterizing ingredient in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case, the percentage such characterizing ingredient shall be declared as a part of the common or usual name of the food. This provision formed the basis for the requirement in the previous version of § 102.33 for declaration of percent of juice, both for total juice and for each individual juice represented on the label.

FDA agrees with comments that stated that declaration of the percentage of individual juices will provide informative labeling. While the agency has decided not to require percentage declaration of represented individual juices in all multiple-juice beverages, it concludes that for multiple-juice beverages that name one or more but not all of the juices present other than in the ingredient list, there is great potential for the label to misrepresent the contribution of the named juice to the product. When the named juice is the predominant juice in the product, FDA considers that the consumer will not be misled with regard to its contribution because naming it will not over emphasize its contribution. However, when the named juice is not the predominant juice, the consumer can be ***2921** misled. Therefore the final regulation, in § 102.33(d), requires that the common or usual name of the product specifically describe the contribution of the named juice if it is not the predominant juice. The agency has provided two ways for the common or usual name to include this information.

In § 102.33(d)(1), the agency has provided that manufacturers can use a product

name that identifies the juice that provides the characterizing flavor and specifically shows that that juice is used to flavor the product (e.g., "raspberry flavored apple and pear juice drink" or "apple and pear juice drink flavored with raspberry juice"). The agency believes that using the term "flavor" with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case. This alternative is consistent with the agency's approach of not requiring percentage total juice declaration for bottled waters that contain juice for flavoring in small amounts (usually less than 2 percent) (see comment 4 of this document). Accordingly, FDA is providing in § 102.33(d)(1) that a multiple-juice beverage may use a product name that specifically shows that the named juice is used as a flavor.

Alternatively, consistent with § 102.5(b), the agency is providing in § 102.33(d)(2) for the declaration of the amount of the named juice in multiple-juice beverages that name one or more but not all of the juices in the product. As explained in the Federal Register of March 14, 1973 (38 FR 6964), the disclosure of the amount of a characterizing ingredient is a material fact.

Among the reasons given in comments that disagreed with the proposed requirement for declaration of percentage of individual juices was the need to have flexibility in the formulation of the beverage to accommodate variations in raw material juices and price changes. The comments included a report that documented that changes in formulation occur frequently and in a significant number of products. The agency is persuaded by the comments that an accommodation is warranted. It agrees that declaration of individual juice content in 1-percent increments is not practicable. Accordingly, FDA is providing in § 102.33(d)(2) that the juice content declaration of individual juices may be made using a 5 percent range, e.g., 2 to 7 percent raspberry juice or 5 to 10 percent cranberry juice. The agency considers that a 5 percent range is large enough to provide for changes in formulation for juices that are present in small amounts.

Comments did not provide specific information on individual juice content, but it is reasonable to assume that a minor juice in a multiple-juice beverage would not be present at greater than about 25 percent of the total product. The 5 percent range is one-fifth of this amount. The agency concludes that a 5 percent range would provide this kind of flexibility to accommodate minor fluctuations in amounts of juice needed to compensate for differences in raw material. In addition, some comments contended that declaration of percent of individual juices in 1-percent increments constitutes an inappropriate disclosure of proprietary formulation information. The agency believes that declaration of individual juice content in 5 percent ranges would in any case not reveal the product formula. Finally, the 5 percent range declaration will provide enough information for consumers to be able to understand the contribution to the product made by the named juice and not be misled into believing that the juice is present in an amount greater than is actually the case.

Accordingly, FDA has provided these two labeling alternatives for multiple-juice

beverages that name one or more but not all of the juices in the product in new § 102.33(d). In addition, the final regulation requires in new § 102.33(d) that the percent individual juice declaration be a part of the name of the product and meet the type size requirements in § 102.5(b)(2).

51. Several comments stated that juice beverages may be made from dehydrated as well as fresh fruits and vegetables in products such as vegetable cocktail, vegetable juice cocktail, juice cocktail, and bloody mary mix. One comment requested clarification that the names "vegetable juice cocktail," "vegetable cocktail juice," and "vegetable cocktail" can be used interchangeably on such products, when they are made from any combination of expressed juice, juice concentrate, and dehydrated fruits and vegetables.

The agency does not have information with which to determine whether beverages made from dehydrated fruits or vegetables differ from beverages made from concentrated or expressed juice. The agency welcomes any data or other information on the nature of beverages made from dehydrated fruits and vegetables, particularly on how they differ from beverages made from expressed or concentrated juice. The agency advises that it will evaluate the labels of such products on a case-by-case basis to determine whether the labeling is misleading. However, FDA advises that irrespective of the form of the vegetable ingredients, the term "vegetable cocktail juice" may not be interchangeable with the other two terms. It uses the word "juice" without a term indicating dilution. Accordingly, it can be used only on beverages that are not diluted juice products. The terms "vegetable juice cocktail" and "vegetable cocktail" would apply to diluted vegetable juice beverages.

C. Vignettes

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a label vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate.

52. Some comments, from both consumers groups and manufacturers, stated that vignettes should depict all juices in a product. Other comments stated that such a provision is not necessary because a descriptive name together with declaration of each juice by order of predominance in the ingredient list and the percent of total juice would provide enough information to ensure that the consumer is adequately informed.

The agency agrees that it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette. The agency believes that a vignette that pictures only some of the fruit or vegetables in the beverage would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice. For example, for a 100 percent juice product consisting of apple, grape, and raspberry juices, in which the

58 FR 2897-01, 1993 WL 1560 (F.R.)

(Cite as: 58 FR 2897)

raspberry juice provides the characterizing flavor, a vignette depicting raspberries would not necessarily be misleading if the statement of identity were "raspberry juice in a blend of apple and grape juice." Similarly, the vignette would not be misleading if the beverage were named "raspberry flavored fruit juice blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice." Moreover, if these three juices were in a beverage containing 50 percent total juice, a vignette picturing raspberries would not be misleading in the presence of a name like "raspberry flavored juice beverage."

Accordingly, FDA is not requiring that vignettes depict the fruits or vegetables for all juices present. However, FDA believes that a vignette that pictures the fruit or vegetable ***2922** sources of all juices present in a product would provide useful information and thus encourages manufacturers to use such vignettes.

Conversely, vegetables or fruits not present in the beverage cannot be depicted in vignettes or other pictorial representations on the label. The agency considers that depicting a fruit or vegetable in a vignette on a juice beverage implies that the fruit or vegetable is in the product, either in the form of a juice or of a natural or artificial flavor of the depicted fruit or vegetable. A vignette that pictures a fruit or vegetable that is not present in the product results in a label that is false and misleading and therefore in violation of section 403(a) of the act.

53. Some comments that wanted all fruits and vegetables pictured in the vignette also requested that the fruits and vegetables be depicted in proportion to the amount of each juice present. However, most comments requested that the agency not impose a specific requirement regarding the relative amounts of the various fruits or vegetables because the relative size and shape of various fruits and vegetables make it difficult to portray by vignette. They stated that both the relative size and the quantity of those fruits and vegetables are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship.

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate. While information in comments emphasized the difficulties in displaying fruits and vegetables quantitatively, there was no information on how useful quantitative displays could be devised. The agency, therefore, is not requiring that fruits and vegetables pictured in vignettes be depicted in proportion to the amount of each juice present.

54. Several comments requested that the agency not make specific requirements regarding flavor characterizations in vignettes. They stated that the taste of a product is best communicated to the consumer through means other than the label vignette alone, and that any requirement should rely on wording to describe product flavor, e.g., "raspberry (flavor) in a blend of ---------- other juices."